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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,882	09/23/2003	Vladimir Feingold	03-114	3596
7590 Lawrence S. Cohen Suite 1220 10960 Wilshire Blvd. Los Angeles, CA 90024		03/23/2007	EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT 3734	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/668,882

Applicant(s)

FEINGOLD ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 is/are rejected.
- 7) ☒ Claim(s) 10 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: NPL document.

DETAILED ACTION

This Action is in response to the Applicant's response to the Requirement for Election/Restriction filed on 15 February 2007.

Election/Restrictions

1. Applicant's election with traverse of Claims 10-17 in the reply filed on 15 February 2007 is acknowledged. The traversal is on the ground(s) that the device and method claims are essentially the same and the claimed device can only perform the claimed method. This is not found persuasive because the device can be used to perform a method other than cutting a corneal flap on an eye, such as removing a thin layer skin when removing a skin irregularity on a different part of the body, like a fingertip.
2. Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 15 February 2007.
3. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

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"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

5. Applicant is reminded of the proper content of an abstract of the disclosure.

6. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

7. The abstract of the disclosure is objected to because it is incomplete. The abstract ends in the middle of a sentence and does not provide a summary of the invention. Correction is required. See MPEP § 608.01(b).

Claim Objections

8. Claim 10 is objected to because of the following informalities: Lines 5-8 run on, please add commas to separate ideas where appropriate. Correction is required.
9. Claim 16 is objected to because of the following informalities: It refers to a non-elected claim (Claim 1). The claim needs to be written in independent form by including the language of Claim 1. Further, lines 12-15 of Claim 1 run on, please add commas to separate ideas where appropriate. Correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
11. Claim 12 and 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
12. It is not clear what the apparatus the Applicant wishes to secure to the positioning ring to in Claim 12.
13. Claim 16 is rejected because of the language contained in Claim 1, lines 12-15. It is not clear what apparatus are moving away from the drive mechanism and what apparatus are moving towards the drive mechanism.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claim 10-12 is rejected under 35 U.S.C. 102(b) as being anticipated by Hellenkamp (US Patent 5,624,456).

16. Hellenkamp'456 discloses a method of creating a corneal flap that includes positioning an eye in a positioning ring (32) having an opening for a cornea to protrude out of (column 7, lines 1-10). Further, the method includes attaching a blade assembly (50) having a blade (71), a guide (55), and a mounting member (110, 115) to a drive mechanism (80). The mounting member has a forward portion (115) and a rearward portion (110). The forward portion is configured so that the blade and guide are mounted so they are in a fixed relationship (see Figure 8). The blade is facing towards the rearward portion (see Figure 8: the cutting edge of the blade is facing towards the left side, with respect to the page, of the rearward portion). Hellenkamp'456 further discloses establishing a start position in which the blade and guide are distal to the drive mechanism (see Figure 9a), then controlling the drive mechanism so it only partially crosses the ring opening (see column 12, lines 12-36). The flap enters space (59) that is towards the drive mechanism.

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17. Claim 11: Hellenkamp'456 discloses that the blade assembly (50) is removable (with the use of coupling member 90 as discussed in column 8, line 58 to column 9, line 44). Further, the fasteners shown are manually fastened, not requiring tools.

18. Claim 12: Hellenkamp'456 discloses that the positioning ring is secured to the driving member (via element 45; see screw inside element 45 in Figure 5c). The attachment does not require tools. (See column 8, lines 11-26).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp'456, as applied to Claim 10, in further view of Steinert (US Patent 5,215,104).

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21. Hellenkamp'456 teaches the limitations of Claim 13, except for a sapphire blade. Steiner'104 teaches a corneal blade made of sapphire because it provides a highly predictable and reliable cut (column 10, lines 30-33). It would have been obvious to one skilled in the art at the time the invention was made to modify the blade taught by Hellenkamp'456 with the sapphire blade taught by Steiner'104 because of the sapphire blades predictable and reliable cutting abilities.

22. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp'456, as applied to Claim 10, in further view of Ross (US Patent 6,358,260).

23. Hellenkamp'456 teaches the limitations of Claims 14 and 15, except for the mounting member containing spaced apart elements.

24. Ross'260 teaches spaced apart mounting elements (22) (shown in Figure 4) because it is used to prevent movement by the blade and the blade guide in more than one direction. The spaced apart elements are integral with the blade and the guide (see Figure 5). It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Hellenkamp'456 with the two spaced apartment because it prevents ensures a good cut by fixing the direction that the device can cut in.

25. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross'260 in further view of Ophthalmology Times E-News "Temporal hinge LASIK flap allows for broad hinge," 13 April 2003 (Ophthalmology Times).

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26. Claim 16: Ross'260 teaches a device that contains a positioning ring (12) having an opening (18) for positioning and retaining a cornea during corneal surgery. The device further contains a blade assembly having a blade (16), a guide (26) and a mounting member (22) for the blade. The mounting member has a forward portion (22) and a rearward portion (64, 66). The forward portion contains the blade and blade guide in a fixed relationship. The rearward portion is used to attach the mounting member to the drive mechanism (62). The drive mechanism moves the blade and the blade guide.

27. Ross'260 does not teach creating a temporal hinge.

28. Ophthalmology Times teaches that creating a temporal hinge during LASIK surgery allows the surgeon to create a broad hinge which creates a larger area of treatable corneal bed than other orientations of the hinge flap. IT would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Ross'260 by creating a temporal hinge because this creates a larger treatable area on the cornea.

Conclusion

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "MJ Hayes", with a long horizontal flourish extending to the right.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER